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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,518

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Gail S. Lebovic

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EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,518	<b>Applicant(s)</b> LEBOVIC ET AL.	
	<b>Examiner</b> Samuel G. Gilbert	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,40,92,95-99,101,105-110,113,114,149-152 and 154-158 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,40,92,95-99,101,105-110,113,114,149-152 and 154-158 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/4/2007, 7/7/2006, 11/11/2005, 6/14/2004</u> .              | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Information Disclosure Statement***

The lined through reference/s was not considered because proper dates have not been supplied.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 40, 92, 95, 96, 98, 99 and 101 are rejected under 35 U.S.C. 102(e) as being anticipated by McDaniel (6,773,390).

Claim 1 - the portion having seeds, radiation sources, -104- is a therapy delivery portion, element -102- is a non-dissolving flexible casing, element -106- is a support member or element -108- is a shield member.

Claim 40 - device -100- is a removable implant, the examiner is taking the therapy portion to be the portion containing sources -104-, the sources as set forth, column 4 lines 38-50, may be iodine-125 which the applicant sets forth as LDR sources.

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The portion of the ribbon including core -106- is considered a non-dissolving flexible tail portion. A catheter for delivery is set forth in column 2 lines 6-13.

Claim 92 - element -102- is an elongate member with a lumen, elements -104- are radiation sources, and element -106- is a support member.

Claim 95 - the support member -106- is enclosed within the tubular member.

Claim 96 - heat shrink tube is set forth in column 4 lines 23-31.

Claim 98 - the support member -106- is flexible to permit curved implantation.

Claim 99 - the lumen includes a first lumen within element -502- for receiving sources -504- and a second lumen within element -518- containing support member -508-.

Claim 101 - seeds 1, 3 and 5 are spaced apart from each other along the tubular member.

Claims 92, 97, 149-152, 154, 157 and 158 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne et al (6,371,904, hereinafter Sirimanne).

Claims 92, 97, 149-151 - The examiner is taking element the coating on element -530- as a tubular member, element -530- includes a material and a coating, the material is considered a support member. The device curves within the body. The radioactive material is adjacent the support material and in a relaxed state the device as shown in Figure 5D has curvature.

Claim 152 - the material is a shape memory metal.

Claim 154 - the coating encases the support material.

Claims 157 and 158 - the helical coil assumes a repeating pattern within the tissue as claimed.

Claims 149-152 and 155-158 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonan et al (7,182,725, hereinafter Bonan).

Claim 149 - the applicant's attention is invited to the embodiments of figures 9A through 10C the catheter is a tubular member, the steering wires -68- and -79- cause bending in a predetermined plane and includes radioactive sources -54-.

Claim 150 - the device curves within the tissue.

Claim 151 - the steering wires are considered support members.

Claim 152 - the steering wire is a metallic strip.

Claim 154 - the steering wires are encased in the catheter as shown in figure 9a and 10c.

Claims 155 - the steering wires and radiation sources are in separate lumens.

Claim 156 - elements -78- in figures 10a through 10c are heat shrink tubes.

Claim 157 - as shown in figures 9b and 10c the sources assume a repeating pattern throughout the arc of the bend in the catheter.

Claim 158 - the device curves within the tissue.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDaniel (69,773,390).

McDaniel teaches a single brachytherapy ribbon as claimed but does not teach more than one tubular members and delivery means for delivering them. Duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Making a plurality of ribbons and providing delivery catheters for them is well within the skill of the art.

Claims 107-110 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al (6,371,904, hereinafter Sirimanne) in view of Tener (4,427,005).

Claim 107-110 - element -530- teaches a brachytherapy device delivered in a straight configuration and deployable in a curved configuration within the breast. Figure 5E shows a straight configuration and Figure 5D shows a curved configuration. However, a plurality of devices are not set forth. Tener teaches using a plurality of devices for treatment of breast tumors. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use a plurality of insertable devices as taught by Sirimanne in a system to treat a plurality of locations in the breast as taught by Tener to gain the advantage of treating the entire breast at one

time as taught by Tener. Needles 75 of Tener teach tubular members for receiving the therapy devices.

Claim 113 - elements -530- include at least one radiation source.

Claim 114 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination Sirimanne et al (6,371,904, hereinafter Sirimanne) and Tener (4,427,005) as applied to claim 107 above, and further in view of McDaniel (6,773,390).

The combination as set forth teaches a device as claimed but does not set forth spaced seeds for the radiation source. McDaniel teaches the use of spaced seeds as a radiation source. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made use seeds as taught by McDaniel for the radiation source of Sirimanne to allow for positioning sources at any desired position along the therapy section and allow for spacers to gain the benefits of controlling the dose rate and lowering the total radioactivity of the source, as set forth in column 5 lines 6-15 of McDaniel.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 4,580,561, 5,498,227, 5,605,530 and 7,232,408 teach related radiation treatment devices.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/  
Primary Examiner, Art Unit 3735

Samuel G. Gilbert  
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Art Unit 3735